

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 120.000: MASSACHUSETTS REGULATIONS FOR THE CONTROL OF RADIATION (MRCR)

120.100: LICENSING OF RADIOACTIVE MATERIAL

120.101: Purpose and Scope

(A) 105 CMR 120.100, 120.500 and 120.770, provide for the licensing of radioactive material. No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to 105 CMR 120.100, 120.500 or 120.770, or as otherwise provided in 105 CMR 120.000.

(B) In addition to the requirements of 105 CMR 120.100, all licensees are subject to the requirements of 105 CMR 120.000, 120.200, 120.750, and 120.770. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of 105 CMR 120.300; licensees using radionuclides in the healing arts are subject to the requirements of 105 CMR 120.500, licensees engaged in land disposal of radioactive material are subject to the requirements of 105 CMR 120.801 through 120.885, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 105 CMR 120.900.

120.102: Definitions

As used in 105 CMR 120.100, the following definitions apply:

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

Decommissioning funding plan means a written document that contains a cost estimate for decommissioning and a description of the method for assuring for decommissioning, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

Facility means the location within one building, vehicle, or under one roof and under the same administrative control (1) at which the possession, use, processing or storage of radioactive material is or was authorized or (2) at which one or more radioactivity-inducing machines are installed or located. Facility may also mean multiple such locations at a site or part of a site.

Financial surety means the method of assuring that sufficient funds will be available at the time of license termination and decommissioning of the facility to cover all costs associated with the decommissioning.

Site means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials.

Site area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

120.103: Source Material

(A) Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20

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of 1% (0.05%) of the mixture, compound, solution, or alloy.

(B) Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(C) Any person is exempt from 105 CMR 120.100 ~~3~~ to the extent that such person receives, possesses, uses, or transfers:

(1) any quantities of thorium contained in

- (a) incandescent gas mantles,
- (b) vacuum tubes,
- (c) welding rods,
- (d) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,
- (e) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium,
- (f) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these, or
- (g) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

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- (2) source material contained in the following products:
 - (a) glazed ceramic tableware, provided that the glaze contains not more than 20% by weight source material,
 - (b) glassware containing not more than 10% by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,
 - (c) glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or
 - (d) piezoelectric ceramic containing not more than 2% by weight source material;
 - (3) photographic film, negatives, and prints containing uranium or thorium;
 - (4) any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;
 - (5) uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:
 - (a) the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission (NRC), authorizing distribution by the licensee pursuant to 10 CFR Part 40,
 - (b) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",¹
 - (c) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",¹ and,
 - (d) this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;
 - (6) natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:
 - (a) the shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and,
 - (b) the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of $\frac{1}{8}$ inch (3.2 mm);
 - (7) thorium contained in finished optical lenses, provided that each lens does not contain more than 30% by weight of thorium, and that this exemption shall not be deemed to authorize either:
 - (a) the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or,
 - (b) the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;
 - (8) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or,
 - (9) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
 - (a) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thorium (thorium dioxide); and,
 - (b) the thorium content in the nickel-thoria alloy does not exceed 4% by weight.
- (D) The exemptions in 105 CMR 120.103(C) do not authorize the manufacture of any of the products described.

¹ The requirements specified in 105 CMR 120.103(C)(5)(b) and (c) need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by 105 CMR 120.000.

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120.120: Types of Licenses

Licenses for radioactive materials are of two types: general and specific.

(A) ~~The Agency issues a specific license to a named person who has filed an application for the license under the provisions of 105 CMR 120.000. General licenses provided in this Part are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the Agency may be required by the particular general license. The general licensee is subject to all other applicable portions of 105 CMR 120.000 and any limitations of the general license.~~

(B) ~~A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular general license. Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of 105 CMR 120.000 as well as any limitations specified in the licensing document.~~

120.122: General Licenses - Radioactive Material Other Than Source Material

(A) Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to 10 CFR Part 31, § 31.3. This general license is subject to the provisions of 105 CMR 120.001 through 120.016, 120.104(A)(2), 120.131, 120.140, 120.150 and 120.200, 120.750, and 120.770. Attention is directed particularly to the provisions of 105 CMR 120.200 which relate to the labeling of containers.

(1) Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

(2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

((B) and (C): Reserved)

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(D) Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere. ~~Certain Measuring, Gauging or Controlling Devices~~

(1) A general license is hereby issued to commercial and industrial firms and ~~to~~ research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to acquire, receive, ~~own~~, possess, use or transfer in accordance with the provisions of 105 CMR 120.122(D)(2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2)(a) The general license in 105 CMR 120.122(D)(1) applies only to radioactive material contained in devices which have been manufactured ~~or initially transferred~~ and labeled in accordance with the specifications contained in

1. a specific license issued by the Agency pursuant to 105 CMR 120.128(D); or,
2. an ~~in accordance with the specifications contained in a~~ **equivalent** specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. ~~which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.~~

(b) The devices must have been received from one of the specific licensees described in 105 CMR 120.122(D)(2)(a) or through a transfer made under paragraph 120.122(D)(3)(i).

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 105 CMR 120.122(D)(1):

(a) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(b) shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however: ;

1. devices containing only krypton need not be tested for leakage of radioactive material; and,
2. devices containing only tritium or not more than 3.7 MBq. (100 microcuries) of other beta and/or gamma-emitting material or 0.37 MBq (ten microcuries) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(c) shall assure that **the tests required paragraph 120.122(D)(3)(b) and** other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

1. in accordance with the instructions provided by the labels; or,
2. by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

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(d) shall maintain records showing compliance with the requirements of 105 CMR 120.122(D)(3)(b) and (c). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. ~~The licensee shall retain these records~~ Records of tests for leakage of radioactive material required by 105 CMR 120.122(D)(3)(b) as follows:

1. each record of a test for leakage of radioactive material required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;
2. each record of a test of the "on-off" mechanism and indicator required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of; and,
3. each record that is required by 105 CMR 120.122(D)(3)(c) shall be maintained for a period of three years from the date of the recorded event or until the device is transferred or disposed of;

~~shall be maintained for one year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by 105 CMR 120.122(D)(3)(b) shall be maintained for one year after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by 105 CMR 120.122(D)(3)(c) shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of;~~

(e) shall immediately suspend operation of the device if there is a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 185 Bq (0.005 microcurie) or more removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices. The device and any radioactive material from the device shall only be disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device or as otherwise approved by the Agency. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Agency within 30 days. Under these circumstances, the criteria set out in 105 CMR 120.243, "Vacating Premises," may be applicable, as determined by the Agency on a case-by-case basis; ~~of upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 185 Bq (0.005 microcurie) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken;~~

(f) shall not abandon the device containing radioactive material;

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(g) shall not export the device containing radioactive material except in accordance with 10 CFR110;

(h)1. shall transfer or dispose of the device containing radioactive material only by export as provided in 105 CMR 120.122(D)(3)(g), by transfer to another general licensee as authorized in 105 CMR 120.122(D)(3)(i), or to a person authorized to receive the device by a specific license issued by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State that authorizes waste collection or as otherwise approved under 105 CMR 120.122(D)(3)(h)3.

2. shall furnish a report to the Agency within 30 days after the transfer of a device to a specific licensee or export. The report shall contain:

- a. the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;
- b. the name, address, and license number of the person receiving the device (license number not applicable if exported); and,
- c. the date of the transfer.

3. shall obtain written Agency approval before transferring the device to any other specific licensee not specifically identified in paragraph 105 CMR 120.122(D)(3)(h)1;

(i) shall transfer the device to another general licensee only if

1. the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of 105 CMR 120.122(D), a copy of 120.122, 120.009, 120.281, and 120.282, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Agency:

- a. the manufacturer's (or initial transferor's) name;
- b. the model number and the serial number of the device transferred;
- c. the transferee's name and mailing address for the location of use; and
- d. the name, title, and phone number of the responsible individual identified by the transferee in accordance with 105 CMR 120.122(D)(3)(l) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or,

2. the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee;

(j) shall comply with the provisions of 105 CMR 120.281 and 120.282 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 105 CMR 120.200 and 120.750;

(k) shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide

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the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director, Radiation Control Program, Massachusetts Department of Public Health, and provide written justification as to why it cannot comply;

(l) shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(m)1. shall register, in accordance with paragraphs 105 CMR 120.122(D)(3)(m)2. and 3., devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph 105 CMR 120.122(D)(3)(m)3.d. represents a separate general licensee and requires a separate registration and fee;

2. if in possession of a device meeting the criteria of paragraph 105 CMR 120.122(D)(3)(m)1. of this section, shall register these devices annually with the Agency and shall pay any prescribed. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Agency. The registration information must be submitted to the Agency within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of paragraph 120.122(D)(3)(m)1. is subject to the bankruptcy notification requirement in 105 CMR 120.131(E);

3. in registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Agency:

- a. name and mailing address of the general licensee;
- b. information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);
- c. name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph 120.122(D)(3)(l);
- d. address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage;
- e. certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information;
- f. certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

4. persons generally licensed by an Agreement State, Licensing State or NRC with respect to devices meeting the criteria in paragraph 120.122(D)(3)(m)1 are not subject to registration requirements if the devices are used in areas subject to Agency jurisdiction for a period less than 180 days in any calendar year. The Agency will not

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request registration information from such licensees.

(n) shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Director, Radiation Control Program, Massachusetts Department of Public Health, within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage;

(o) may not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph 120.122(D)(3)(b) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(4) The general license in 105 CMR 120.122(D)(1) does not authorize the manufacture or import of devices containing radioactive material.

[Note: Persons possessing radioactive material in devices under a general license in 10 CFR. 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of 10 CFR. 31.5 in effect on January 14, 1975.]

~~except as provided in 105 CMR 120.122(D)(3)(h), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;~~

~~(h) shall transfer the device to another general licensee only:~~

~~1. where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of 105 CMR 120.100 and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Agency and the transferee; or~~

~~2. where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and~~

~~(i) shall comply with the provisions of 105 CMR 120.281 and 120.282 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 105 CMR 120.200 and 120.750.~~

~~(5) The general license provided in 105 CMR 120.122(D)(1) is subject to the provisions of 105 CMR 120.005 through 120.016, 120.131, 120.140, 120.150, and 120.770.~~

120.125: General Requirements for the Issuance of Specific Licenses

(A) A license application will be approved only if the Agency determines that:

(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested

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in accordance with 105 CMR 120.000 in such a manner as to minimize danger to public health and safety or property;
(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

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- (3) the issuance of the license will not be inimical to the health and safety of the public; and,
- (4) the applicant satisfies any applicable special requirements in 105 CMR 120.126, 120.127, 120.128, 120.300, 120.500, 120.620 120.800, 120.890 or 120.900.

(B) Environmental Report, Commencement of Construction.

- (1) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, a license application shall be reviewed and approved by the Agency before commencement of construction of the plant or facility in which the activity will be conducted. Issuance of the license shall be based upon a consideration by the Agency of the environmental, economic, technical and other benefits in comparison with the environmental costs and available alternatives and a determination that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values;
- (2) Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in 105 CMR 120.125(B) the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(C) Financial Surety Arrangements and Recordkeeping for Decommissioning Reclaiming Sites. For purposes of 105 CMR 120.125(C), "reclaiming" shall mean returning property to a condition or state such that the property no longer presents a public health or safety hazard or threat to the environment.

~~AGENCY NOTE: For purposes of 105 CMR 120.125(C), the term "reclaiming" includes but is not limited to those activities necessary to decommission the licensed facility (i.e., to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license).~~

- (1) Unless exempted by 105 CMR 120.125(C)(10 ~~3~~), issuance, renewal or amendment of a license shall be dependent upon satisfactory financial surety arrangements to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements of M.G.L. c. 111H §9 and 105 CMR 120.000.
- (2) ~~(a)~~ Each applicant for a specific license authorizing the possession and use of unsealed radioactive material with a half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in 105 CMR 120.196: *Appendix B*, Table II shall submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6 ~~+~~)(~~e~~). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in 105 CMR 120.196: *Appendix B*, Table II.
- (3) ~~(b)~~ Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 105 CMR 120.125(C)(5 ~~+~~)(~~d~~) shall either:
 - (a) ~~1~~-submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6 ~~+~~)(~~e~~); or
 - (b) ~~2~~-submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 105 CMR 120.125(C)(5 ~~+~~)(~~d~~) using one of the methods described in 105 120.125(C)(7 ~~+~~)(~~f~~). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued, but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7 ~~+~~)(~~f~~) is to be submitted to the Agency.
- (4) (a) ~~(e)~~ Each holder of a specific license issued on or after March 11, 1994, which is of

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a type described in 105 CMR 120.125(C)(~~2 + (a)~~) or (~~3 b~~), shall provide financial assurance for decommissioning in accordance with the criteria set forth in 105 CMR 120.125(C)(1) ~~through 120.125(C)(8)~~.

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- (b) ~~2~~ Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(2) ~~+~~(a) shall submit, on or before March 11, 1995, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to ~~\$750,000~~ 1,125,000, in accordance with the criteria set forth in this part. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.
- (c) ~~3~~ Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(3) ~~+~~(b) shall submit, on or before March 11, 1995, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through 120.125(C)(8).
- (d) Waste collectors and waste processors, as defined in 10 CFR part 20, Appendix G must establish an Agency-approved decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility. The decommissioning funding plan must include the cost of disposal of the maximum radioactivity (curies) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material that could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 105 CMR 120.200. The decommissioning funding plan must be submitted by (six months following the effective date of the rule).
- (5) ~~(d)~~ Table of Required Amounts of Financial Assurance for Decommissioning by Quantity of Material:
- | | | |
|-----|---|----------------------------|
| (1) | Greater than 10^4 but less than or equal to 10^5 times the applicable quantities in 105 CMR 120.196: <i>Appendix B</i> , Table II in unsealed form.
(For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2) + (a), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.) | \$750 1,125,000 |
| (2) | Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in 105 CMR 120.196: <i>Appendix B</i> , Table II in unsealed form.
(For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2) + (a), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.) | \$150 225,000 |
| (3) | Greater than 10^{10} times the applicable quantities in 105 CMR 120.196: <i>Appendix B</i> , Table II in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2) + (a), divided by 10^{10} is greater than 1.) | \$75 113,000 |
- (a) Licensees required to submit the \$1,125,000 amount must do so by (effective date of the rule)
- (b) Licensees required to submit the \$113,000 or \$225,000 amount must do so by (six months following the effective date of the rule).
- (6) ~~(e)~~ Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 105 CMR 120.125(C)(7) ~~+~~(f), including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.
- (7) ~~(f)~~ Financial assurance for decommissioning must be provided by one or more of the following methods:
- (a) ~~+~~ Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee

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assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(b) ~~2. A Surety Method.~~ A surety method, insurance or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default:-

1. A surety method may be in the form of a surety bond; ~~issued by a corporate surety company authorized to transact business in the commonwealth; or~~

2. ~~An irrevocable~~ letter of credit, or line of credit; ~~or~~

3. A parent company guarantee of funds for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix D*. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of ~~this part~~ 105 CMR 120.125(C).

a. ~~For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix E*.~~

b. ~~For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix F*.~~

c. ~~For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix G*.~~

4. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

a. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

b. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

c. The surety method or insurance must remain in effect until the Agency has terminated the license.

(c) ~~3. An External Sinking Fund.~~ An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 105 CMR 120.125(C)(7 +)(b f)(2).

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- (d) ~~4.~~Statement of Intent. In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount pursuant to 105 CMR 120.125(C)(~~5+~~)(~~+~~), and indicating that funds for decommissioning will be obtained when necessary.
- (8) ~~(g)~~ Each person licensed under 105 CMR 120.100 shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:
- (a) ~~+~~Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas, as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.
 - (b) ~~2.~~As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.
 - (c) ~~3.~~Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:
 - 1. ~~a.~~ all areas designated and formerly designated restricted areas as defined in 105 CMR 120.005;
 - 2. ~~b.~~ all areas outside of restricted areas that require documentation under 105 CMR 120.125(C)(~~8+~~)(~~a g~~)(~~+~~);
 - 3. ~~c.~~ all areas outside of restricted areas where current and previous wastes have been buried as documented under 105 CMR 120.269; and,

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4. ~~4.~~ all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 105 CMR 120.252.
- (d) ~~4.~~Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.
- (9 ~~2~~) The following specific licensees are required to make financial surety arrangements:
 - (a) major processors;
 - (b) waste handling licensees;
 - (c) former U.S. Atomic Energy Commission or NRC licensed facilities; and,
 - (d) all others except persons exempt pursuant to 105 CMR 120.125(C)(10 ~~3~~).
- (10 ~~3~~) The following persons are exempt from the requirements of 105 CMR 120.125(C)(1) through 120.125(C)(8):
 - (a) persons authorized to possess no more than 1,000 times the quantity specified in 105 CMR 120.196: *Appendix B, Table 1* or combination of radioactive material listed therein as given in 105 CMR 120.196: *Appendix B, Table I, Note 1*;
 - (b) persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

(D) Licensing ~~Requirements to the Manufacture or Initially Transfer and Distribution of Devices~~ ~~Containing Radioactive Material~~ to Persons Generally Licensed Under 105 CMR 120.122(D).

- (1) An application for a specific license to manufacture or ~~initially transfer~~ ~~distribute~~ devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 105 CMR 120.122(D) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:
 - (a) the applicant satisfies the general requirements of 105 CMR 120.125;
 - (b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
 1. the device can be safely operated by persons not having training in radiological protection,
 2. under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in 1 year a dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A), and
 3. under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	(150 mSv) (15 rems)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	(2 Sv) (200 rems)
Other organs	(500 mSv) (50 rems); and,
 - (c) each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:
 1. instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information;

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2. the requirements, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and,
3. the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

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~~a.~~The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. [The model, serial number, and name of the manufacturer or distributor may be omitted from the label provided the information is elsewhere specified in labeling affixed to the device.]

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

[Note: Devices licensed under 10 CFR 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.]

(d) each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in 105 CMR 120 237, and the name of the manufacturer or initial distributor.

(e) each device meeting the criteria of 105 CMR 120 122(D)(3)(m)1., bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in 105 CMR 120 237.

b. The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. [The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.]

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

[Note: Devices licensed under 10 CFR 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.]

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by

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performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

- (a) primary containment or source capsule;
- (b) protection of primary containment;
- (c) method of sealing containment;
- (d) containment construction materials;
- (e) form of contained radioactive material;
- (f) maximum temperature withstood during prototype tests;
- (g) maximum pressure withstood during prototype tests;
- (h) maximum quantity of contained radioactive material;
- (i) radiotoxicity of contained radioactive material; and,
- (j) operating experience with identical devices or similarly designed and constructed devices. 120.128: continued

(3) In the event the applicant desires that the general licensee under 105 CMR 120.122(D), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A).

(4) Each person licensed under 105 CMR 120.128(D) to ~~distribute~~ **initially transfer** devices to generally licensed persons shall:

(a) if a device containing radioactive material is to be transferred for use under the general license contained in 105 CMR 120.122 (D), each person that is licensed under 105 CMR 120.128 (D) shall provide the information specified in 120.128(D)(4) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

- 1. a copy of the general license contained in 105 CMR 120.122 (D); if paragraphs 120.122(D)(3)(b) through (d) do not apply to the particular device, those paragraphs may be omitted;
- 2. a copy of 105 CMR 120.122, 120.009 (A), 120.281, and 120.282;
- 3. a list of the services that can only be performed by a specific licensee; and,
- 4. information on acceptable disposal options including estimated costs of disposal;

(b) if radioactive material is to be transferred in a device for use under an equivalent general license of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State each person that is licensed under 105 CMR 120.128 (D) shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

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1. a copy of NRC or Agreement State regulations equivalent to 105 CMR 120.122(D), 120.009 (A), 120.281, and 120.282. If a copy of the Agency regulations is provided to a prospective general licensee in lieu of the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the U.S. Nuclear Regulatory Commission, the Agreement State; or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;
2. a list of the services that can only be performed by a specific licensee;
3. information on acceptable disposal options including estimated costs of disposal; and,
- 4 the name or title, address, and phone number of the contact at the U.S. Nuclear Regulatory Commission, the Agreement State, or Licensing State from which additional information may be obtained; ~~furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulation equivalent to 105 CMR 120.122(D), or alternatively, furnish a copy of the general license contained in 105 CMR 120.122(D) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State, or the Licensing State. If a copy of the general license in 105 CMR 120.122(D) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State under requirements substantially the same as those in 105 CMR 120.122(D);~~

(c) an alternative approach to informing customers may be proposed by the licensee for approval by the Agency;

(d) each device that is transferred after February 19, 2002 must meet the labeling requirements in 120.128(D)(1)(c) through (e);

(e) if a notification of bankruptcy has been made under 105 CMR 120.131(E) or the license is to be terminated, each person licensed under 105 CMR 120.128(D) shall provide, upon request, to the Agency and to any appropriate Agreement State or NRC, records of final disposition required under 105 CMR 120.128(D)(5)(c).

(5) Each person licensed under 105 CMR 120.128(D) to initially transfer devices to generally licensed persons shall comply with the requirements of 105 CMR 120.128(D)(5).

(a) The person shall report to the Agency all transfers of devices to persons for use under the general license in 105 CMR 120.122(D) and all receipts of devices from persons licensed under 105 CMR 120.122(D). The report must be submitted on a quarterly basis on NRC Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

1. The required information for transfers to general licensees includes:

- a. the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;
- b. the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
- c. the date of transfer;

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- d. the type, model number, and serial number of the device transferred; and,
 - e. the quantity and type of byproduct material contained in the device.
 2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
 3. For devices received from a 105 CMR 120.122(D) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
 4. If the licensee makes changes to a device possessed by a CMR 120.122(D) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
 5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.
 6. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
 7. If no transfers have been made to U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.
 8. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency.
- (b) The person shall report all transfers of devices to persons for use under a general license in the U.S. Nuclear Regulatory Commission's, an Agreement State's, or a Licensing State's regulations that are equivalent to CMR 120.122(D) and all receipts of devices from general licensees in the U.S. Nuclear Regulatory Commissions, an Agreement State's, or a Licensing State's jurisdiction to the responsible agency. The report must be submitted on Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.
1. The required information for transfers to general licensees includes:
 - a. the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;
 - b. the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
 - c. the date of transfer;
 - d. the type, model number, and serial number of the device transferred; and,

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e. the quantity and type of byproduct material contained in the device.

2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

3. For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

4. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

6. The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

7. If no transfers have been made to U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

8. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 105 CMR 120.128(D)(5). Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

~~report to the Agency all transfers of such devices to persons for use under the general license in 105 CMR 120.122(D). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under 105 CMR 120.122(D) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;~~

~~(d) furnish reports to other agencies:~~

~~1. Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR Part 31, § 31.5;~~

~~2. Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 105 CMR 120.128(D) for use under a general license in that State's regulations equivalent to 105 CMR 120.122(D);~~

~~3. Such reports shall identify each general licensee by name and address, an individual by name and/or position~~

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~~who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.~~

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~~4. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission;~~

~~5. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency; and;~~

~~(e) keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 105 CMR 120.122(D), or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of 105 CMR 120.128(D)(4)(d). The records required by 105 CMR 120.128(D)(4)(e) shall be maintained for a period of five years from the date of the recorded event.~~

(J) Manufacture, Preparation, or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Medical Use Under 105 CMR 120.500.

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 105 CMR 120.500 will be approved if:

- (a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
- (b) the applicant submits evidence that the applicant is at least one of the following:
 - 1. registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer; or
 - 2. registered or licensed with a state agency as a drug manufacturer; or,
 - 3. licensed as a pharmacy by a State Board of Pharmacy; or,
 - 4. operating as a nuclear pharmacy pursuant to 247 CMR 13.00.
- (c) the applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and,

(d) the applicant satisfies the following labeling requirements:

~~1. (d) 1.~~ a label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL", the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days the time may be omitted.

2. a label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee pursuant to 105 CMR 120.128(J)(1)(b)3. **or (b)4.:**

(a) may prepare radioactive drugs for medical use, as defined 105 CMR 120.502, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 105 CMR 120.128(J)(2)(b) and 120.128(J)(2)(c), or an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519 ~~θ~~.

(b) may allow a pharmacist to work as an authorized nuclear pharmacist if:

- 1. if this individual qualifies as an authorized nuclear pharmacist as defined in 105 CMR 120.502; or,

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2. this individual meets the requirements specified in 105 CMR 120.526 80(B) and 120.529 77 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or,
 3. this individual is designated as an authorized nuclear pharmacist in accordance with 105 CMR 120.128(J)(2)(~~d~~ e).
- (c) the actions authorized in 105 CMR 120.128(J)(2)(a) and (2)(b) are permitted in spite of more restrictive language in license conditions.
- (d) may designate a pharmacist, as defined in 105 CMR 120.005, as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by NRC under 10 CFR part 32.
- (e) shall provide to the Agency a copy of each individual's certification by the Board of Pharmaceutical Specialties, the NRC or Agreement State or Licensing State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 105 CMR 120.128(J)(2)(b)1. and (2)(b)3., the individual to work as an authorized nuclear pharmacist.
- (3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:
- (a) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary: and
 - (b) check each instrument for constancy and proper operation at the beginning of each day of use.
- (4) Nothing in 105 CMR 120.128(J) relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(K) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.⁵ An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 105 CMR 120.100 for the uses listed in 105 CMR 120.533 will be approved if:

- (1) the applicant satisfies the general requirements specified in 105 CMR 120.125;

⁵ Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to 105 CMR 120.533 may submit the pertinent information specified in 105 CMR 120.128(K).

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- (2) the applicant submits evidence that:
 - (a) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or,
 - (b) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;
- (3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;
- (4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and,
- (5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:
 - (a) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit; and,
 - (b) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to 105 CMR 120.533 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by 105 CMR 120.128(K) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(L) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 105 CMR 120.500 for use as a calibration or reference source or for the uses listed in 105 CMR 120.559, 120.568 4+ and 120.570 43 will be approved if:

- (1) the applicant satisfies the general requirements in 105 CMR 120.125;
- (2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - (a) the radioactive material contained, its chemical and physical form, and amount;;
 - (b) details of design and construction of the source or device;;
 - (c) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;;
 - (d) for devices containing radioactive material, the radiation profile of a prototype device;;
 - (e) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;;
 - (f) procedures and standards for calibrating sources and devices;;
 - (g) legend and methods for labeling sources and devices as to their radioactive content;; and,
 - (h) instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;
- (3) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the ~~source or device is licensed by the~~

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Agency ~~has approved the~~ for distribution ~~of the (name of source or device)~~ to persons licensed ~~to use radioactive material identified in~~ pursuant to 105 CMR 120.523 ~~00~~, 120.559, 120.568, ~~41~~ and 120.570 ~~43~~ or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State; ~~provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;~~

(4) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and,

(5) in determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:

- (a) primary containment or source capsule;
- (b) protection of primary containment;
- (c) method of sealing containment;
- (d) containment construction materials;
- (e) form of contained radioactive material;
- (f) maximum temperature withstood during prototype tests;
- (g) maximum pressure withstood during prototype tests;
- (h) maximum quantity of contained radioactive material;
- (i) radiotoxicity of contained radioactive material; and,
- (j) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(N) Special Requirements for License to Manufacture, Import or Initially Distribute Sealed Sources or Devices Containing Sealed Sources to Persons Having a Specific License.

(1) An application for license to manufacture, import (NARM only) or initially distribute sealed sources or devices containing sealed sources for initial transfer to persons having a specific license to receive such sealed sources or devices will be approved subject to the following conditions:

- (a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
- (b) the licensee subject to 105 CMR 120.128(N) shall not transfer a sealed source or device containing a sealed source to any person except in accordance with the requirements of 105 CMR 120.140.

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(2) Any manufacturer, importer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the Agency for evaluation of radiation safety information about its product and for filing an evaluation sheet in ~~the U.S. Department of Health and Human Services "Radioactive Material Reference Manual" or in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices"~~.

(a) A request for evaluation of a sealed source or device containing a sealed source shall be submitted in duplicate and shall include information required by 105 CMR 120.128(N)(2)(b) or (c), as applicable, demonstrating that the radiation safety properties of such source or device will not endanger public health and safety or property.

(b) A request for evaluation of a sealed source shall include the following radiation safety information:

1. proposed uses for the sealed source;
2. chemical and physical form and maximum quantity of radioactive material in the sealed source;
3. details of design of the sealed source, radiation and its shielding including blueprints, engineering drawings or annotated drawings;
4. details of construction of the sealed source including a description of materials used in construction;
5. radiation profile of a prototype sealed source;
6. procedures for and results of prototype testing;
7. details of quality control procedures to be followed in manufacture;
8. a description or facsimile of labeling to be affixed to the sealed source;
9. leak testing procedures; and,
10. any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the sealed source, as required by 105 CMR 120.125.

(c) A request for evaluation of a device containing a sealed source shall include the following radiation safety information:

1. proposed uses for the device;
2. manufacturer, model number, chemical and physical form and maximum quantity of radioactivity in the sealed source or sources to be used in the device;
3. details of design of the sealed source, including blueprints, engineering drawings or annotated drawings;
4. details of construction of the sealed source including a description of materials used in construction;
5. radiation profile of a prototype device;
6. procedures for and results of prototype testing;
7. details of quality control procedures to be followed in manufacture;
8. a description or facsimile of labeling to be affixed to the device;
9. leak testing procedures;
10. a description of potential hazards in installation, service, maintenance, handling, use and operation of the device;
11. information about installation, service and maintenance procedures;
12. handling, operating and safety instructions; and
13. any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the device as required by 105 CMR 120.125.

(d) When evaluating a sealed source or device, the Agency will apply the radiation safety criteria described in 10 CFR 32.210(d), published January 1, 1993, ~~exclusive of subsequent amendments or editions~~.

(e) The person submitting a request for evaluation of a product shall manufacture and distribute the product in accordance with:

1. the statements and representations, including the quality control program, described in the request; and

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2. the provisions of the evaluation sheet prepared by the Agency and submitted to ~~the U.S. Department of Health and Human Services, for filing in the "Radioactive Material Reference Manual" or in the U.S. Nuclear Regulatory Commission, for filing in the "Registry of Radioactive Sealed Sources and Devices".~~

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120.130: Issuance of Specific Licenses

(A)(1) Upon a determination that an application meets the requirements of M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P and the regulations of the Agency, and upon payment of the required fee **as specified in 105 CMR 120.130(A)(2)**, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) Each initial application for a license or a certificate of registration for which a fee is established by the Executive Office for Administration and Finance in 801 CMR 4.00 shall be accompanied by a non-refundable fee, payable to the Commonwealth of Massachusetts, in the amount specified for the corresponding annual fee. Thereafter, the Radiation Control Program will issue an annual fee invoice based on the applicable annual fee specified in 801 CMR 4.00. Fees are payable within thirty (30) days after receipt of a fee invoice.

(B) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to 105 CMR 120.100 as it deems appropriate or necessary in order to:

- (1) minimize danger to public health and safety or property;
- (2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
- (3) prevent loss or theft of material subject to 105 CMR 120.100.

120.131: Specific Terms and Conditions of Licenses

(A) Each license issued pursuant to 105 CMR 120.100 shall be subject to all the provisions of M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, now or hereafter in effect, and to all rules, regulations, ~~and orders~~ of the Agency **and license conditions as provided for in 105 CMR 120.130(B)**.

(B) No license issued or granted under 105 CMR 120.100 and no right to possess or utilize radioactive material granted by any license issued pursuant to this Part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, now or hereafter in effect, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(C) Each person licensed by the Agency pursuant to 105 CMR 120.100 shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(D) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(E) Each licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

- (1) the licensee;
- (2) an entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or
- (3) an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

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(F) The notification specified in 105 CMR 120.131(E) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

120.132: Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas

(A) Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 105 CMR 120.133 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(B) Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency Order.

(C) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

- (1) Limit actions involving radioactive material to those related to decommissioning; and,
- (2) Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.

(D) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in 105 CMR 120.013, each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by 105 CMR 120.132(GF)(1) and begin decommissioning upon approval of that plan if-

- (1) The license has expired pursuant to 105 CMR 120.132(A) or (B); or,
- (2) The licensee has decided to permanently cease principal activities, as defined in 105 CMR 120.005, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements; or,
- (3) No principal activities under the license have been conducted for a period of 24 months; or,
- (4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

(E) Coincident with the notification required by 105 CMR 120.132(D), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 105 CMR 120.125(C) in conjunction with a license issuance or renewal or as required by 105 CMR 120.132. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to 105 CMR 120.132(G)(4)(e).

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Agency.

(FE) The Agency may grant a request to extend the time periods established in 105 CMR 120.132(D) if the Agency determines

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that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 105 CMR 120.132(D). The schedule for decommissioning set forth in 105 CMR 120.132(D) may not commence until the Agency has made a determination on the request.

- (G~~F~~) (1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor have not been previously approved by the Agency and these procedures could increase potential health and Safety impacts to workers or to the public, such as in any of the following cases:
- (a) procedures would involve techniques not applied routinely during cleanup or maintenance operations;
 - (b) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
 - (c) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or,
 - (d) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.
- (2) The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 105 CMR 120.132(D) if the Agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.
- (3) Procedures such as those listed in 105 CMR 120.132(G~~F~~)(1) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.
- (4) The proposed decommissioning plan for the site or separate building or outdoor area must include:
- (a) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
 - (b) a description of planned decommissioning activities;
 - (c) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
 - (d) a description of the planned final radiation survey; and,

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- (e) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.
 - (f) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in 105 CMR 120.132(~~HH~~).
- (5) The proposed decommissioning plan will be approved by the Agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.
- (~~HG~~) (1) Except as provided in 105 CMR 120.132(~~HH~~), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.
- (2) Except as provided in 105 CMR 120.132(~~HH~~), when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.
- (~~HH~~) The Agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Agency determines that the alternative is warranted by consideration of the following:
- (1) whether it is technically feasible to complete decommissioning within the allotted 24-month period;
 - (2) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;
 - (3) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
 - (4) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and,
 - (5) other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.
- (~~JH~~) As the final step in decommissioning, the licensee shall-
- (1) Certify the disposition of all licensed material including accumulated wastes, by submitting a completed Agency Form MRCP 120.100-3 or equivalent information; and,
 - (2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate-
 - (a) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters -removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and,
 - (b) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.
- (~~KH~~) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:
- (1) radioactive material has been properly disposed;

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- (2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and,
- (3) (a) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Agency requirements; or,
 - (b) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Agency requirements.

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120.133: Renewal of Licenses

(A) Applications for renewal of specific licenses shall be filed in accordance with 105 CMR 120.124.

(B) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Agency.

120.134: Amendment of Licenses at Request of Licensee

(A) Applications for amendment of a license shall be filed in accordance with 105 CMR 120.124 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

(B) An invoice for an amendment fee will be issued on receipt of a request to amend a license. The amendment will not be issued until after the invoiced amount has been paid.

120.135: Agency Action on Applications to Renew or Amend

In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in 105 CMR 120.125, 120.126, 120.127, and 120.128 and in 120.300, 120.500, 120.800 or 120.900, as applicable.

~~Licenses Held at the Time of the Effective Date of 105 CMR 120.000~~

120.136: Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of 105 CMR 120.000

Any person who, on March 21, 1997, date of the Agreement between the Commonwealth and the NRC pursuant to section 274b of the Atomic Energy Act of 1954, as amended (42 USC 2021), possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like license issued under 105 CMR 120.136 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, such license to expire either 90 days after receipt from the Agency of a notice of expiration of such license, or on the date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

120.137: Persons Possessing Naturally Occurring and Accelerator-Produced Radioactive Material (NARM) on Effective Date of 105 CMR 120.000

Any person who, on the effective date of 105 CMR 120.000, possesses NARM for which a specific license is required by M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P or 105 CMR 120.137 shall be deemed to possess such a license issued under M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P and 105 CMR 120.137. Such license shall expire 90 days after the effective date of 105 CMR 120.000; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the Agency.

120.140: Transfer of Material

(A) No licensee shall transfer radioactive material except as authorized pursuant to 105 CMR 120.140.

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(B) Except as otherwise provided in his license and subject to the provisions of 105 CMR 120.140(C) and (D), any licensee may transfer radioactive material:

- (1) to the Agency;[Only after receiving prior approval from the Agency.]
- (2) to the U.S. Department of Energy;
- (3) to any person exempt from 105 CMR 120.000 to the extent permitted under such exemption;
- (4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, an Agreement State, or a Licensing State; or,
- (5) as otherwise authorized by the Agency in writing.

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(C) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(D) Any of the following methods for the verification required by 105 CMR 120.140(C) is acceptable:

- (1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate.
- (2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.
- (3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within ten days.
- (4) The transferor may obtain other information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration.
- (5) When none of the methods of verification described in 105 CMR 120.140(D)(1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.

(E) Shipment and transport of radioactive material shall be in accordance with the provisions of 105 CMR 120.770.

120.142: Reporting Requirements

(A) Immediate report. Each licensee shall notify the Agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, *etc.*).

(B) Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

- (1) An unplanned contamination event that:
 - (a) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
 - (b) Involves a quantity of material greater than five times the lowest annual limit on intake specified in 105 CMR 120.296: *Appendix B* for the material; and,
 - (c) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
- (2) An event in which equipment is disabled or fails to function as designed when:
 - (a) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences

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- of an accident;
 - (b) The equipment is required to be available and operable when it is disabled or fails to function; and,
 - (c) No redundant equipment is available and operable to perform the required safety function.
- (3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

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(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

- (a) The quantity of material involved is greater than five times the lowest annual limit on intake specified in 105 CMR 120.296: *Appendix B* for the material; and,
- (b) The damage affects the integrity of the licensed material or its container.

(C) Preparation and Submission of Reports. Reports made by licensees in response to the requirements of 105 CMR 120.142 must be made as follows:

(1) Licensees shall make reports required by 105 CMR 120.142(A) and (B) by telephone to the Agency at ~~(617) 727-6214~~ during normal working hours or the Nuclear Incident Advisory Team (NIAT) ~~(617) 727-9710~~, at all other times. To the extent that the information is available at the time of notification, the information provided in these reports must include:

- (a) The caller's name and call back telephone number;
- (b) A description of the event, including date and time;
- (c) The exact location of the event;
- (d) The isotopes, quantities, and chemical and physical form of the licensed material involved; and,
- (e) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by 105 CMR 120.142(A) or (B) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Massachusetts Department of Public Health, Radiation Control Program, ~~174 Portland Street, Boston, MA 02114~~. The report must include the following:

- (a) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- (b) The exact location of the event;
- (c) The isotopes, quantities, and chemical and physical form of the licensed material involved;
- (d) Date and time of the event;
- (e) Corrective actions taken or planned and the results of any evaluations or assessments; and,
- (f) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

120.190: Reciprocal Recognition of Licenses

(A) Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to 105 CMR 120.000, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State, and issued by the Agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

- (a) the licensing document does not limit the activity authorized by such document to specified installations or locations;
- (b) the out-of-state licensee notifies the Agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three day period would impose

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an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 105 CMR 120.190(A)(1);

- (c) the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;
- (d) the out-of-state licensee supplies such other information as the Agency may request; and
- (e) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 105 CMR 120.190(A)(1) except by transfer to a person:

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120.190: continued

1. specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission to receive such material; or,
 2. exempt from the requirements for a license for such material under 105 CMR 120.104(A).
- (2) Notwithstanding the provisions of 105 CMR 120.190(A)(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in 105 CMR 120.122(D)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:
- (a) ~~[Reserved] such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;~~
 - (b) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;
 - (c) such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and,
 - (d) the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 105 CMR 120.122(D) or in equivalent regulations of the Agency having jurisdiction over the manufacture and distribution of the device.
- (3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(B) Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material.

- (1) Subject to 105 CMR 120.000, any person who holds a specific license from a Licensing State, and issued by the Agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:
- (a) the licensing document does not limit the activity authorized by such document to specified installations or locations;
 - (b) the out-of-state licensee notifies the Agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 105 CMR 120.190(B)(1);
 - (c) the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;
 - (d) the out-of-state licensee supplies such other information as the Agency may request; and
 - (e) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 105 CMR 120.190(B)(1) except by transfer to a person:
 1. specifically licensed by the Agency or by another Licensing State to receive such material; or,

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2. exempt from the requirements for a license for such material under 105 CMR 120.104.

(2) Notwithstanding the provisions of 105 CMR 120.190(B)(1), any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in 105 CMR 120.122(D)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:

- (a) ~~[Reserved] such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;~~
 - (b) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;
 - (c) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and,
 - (d) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 105 CMR 120.122(D) or in equivalent regulations of the Agency having jurisdiction over the manufacture and distribution of the device.
- (3) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(C) Exceptions to the General License

(1) ~~The general license granted in 105 CMR 120.190(A) and 120.190(B) to conduct activities in the State does not include activities in areas of exclusive Federal jurisdiction within the State or offshore waters.~~

(2) ~~Authorization for use of radioactive materials in areas of exclusive Federal jurisdiction within the State or offshore waters may be obtained from the U.S. Nuclear Regulatory Commission as provided for in 10 CFR 150.20.~~

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120.198: Appendix D --

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test.

(A) To pass the financial test, the parent company must meet the criteria of either II.A.1 or II.A.2:

(1) The parent company must have:

- (a) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and,
- (b) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and,
- (c) Tangible net worth of at least \$10 million; and,
- (d) Assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

(2) The parent company must have:

- (a) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's; and,
- (b) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and,
- (c) Tangible net worth of at least \$10 million; and,
- (d) Assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

(B) The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(C) (1) After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(2) If the parent company no longer meets the requirements of II.A, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in the Commission's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

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III. Parent Company Guarantee. The terms of a parent company guarantee that an applicant or licensee obtains must provide that:

(A) The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Agency, as evidenced by the return receipts.

(B) If the licensee fails to provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the licensee and the Agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(C) The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license.

(D) If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

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120.198 9: Appendix E --

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of 105 CMR 120.198 9: *Appendix E*, Section II. The terms of the self-guarantee are in 105 CMR 120.198 9: *Appendix E*, Section III. 105 CMR 120.198 9: *Appendix E* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) To pass the financial test, a company must meet all of the following criteria:

- (1) Tangible net worth at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
- (2) Assets located in the United States amounting to at least 90% of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
- (3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), Aaa, As, or A as issued by Moodys.

(B) To pass the financial test, a company must meet all of the following additional requirements:

- (1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.
- (2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
- (3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(C) If the licensee no longer meets the requirements of 105 CMR 120.198 9: *Appendix E*, Section II.A, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations within 120 days of such notice.

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III. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The parent company guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipts.

(B) The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

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120.198 9: continued

(C) The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

(D) The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

(E) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of 105 CMR 120.198 9: *Appendix E*, Section II.(A).

(F) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

120.198: Appendix F --

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES FOR PROVIDING REASONABLE
ASSURANCE OF FUNDS FOR DECOMMISSIONING BY COMMERCIAL COMPANIES THAT HAVE NO OUTSTANDING RATED
BONDS

I. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of 105 CMR 120.198: *Appendix F*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix F*, Section III. 105 CMR 120.198: *Appendix F* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) To pass the financial test, a company must meet all of the following criteria:

- (1) Tangible net worth greater than \$10 million, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
- (2) Assets located in the United States amounting to at least 90% of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
- (3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

(B) In addition, to pass the financial test, a company must meet all of the following additional requirements:

- (1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform The Agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
- (2) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.
- (3) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix F*, Section II.A, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal

year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

(B) The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

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(C) The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

(D) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

120.198 : Appendix G --

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEE FOR PROVIDING REASONABLE ASSURANCE
OF FUNDS FOR DECOMMISSIONING BY NONPROFIT COLLEGES, UNIVERSITIES, AND HOSPITALS

I. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of 105 CMR 120.198: *Appendix G*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix G*, Section III. 105 CMR 120.198: *Appendix G* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) For colleges and universities, to pass the financial test a college or university must meet either the criteria in 105 CMR 120.198: *Appendix G*, Section II.(A)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(A)(2).

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(B) For hospitals, to pass the financial test a hospital must meet either the criteria in 105 CMR 120.198: *Appendix G*, Section II.(B)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(B)(2):

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a

self-guaranteeing license.

(C) In addition, to pass the financial test, a licensee must meet all the following requirements:

(1) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

(2) After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to the Agency of its intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

(B) The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

(C) The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

(D) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(D) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of ``A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service.

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(C) The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

(D) The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

(E) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of 105 CMR 120 199: *Appendix E*, Section II.(A).

(F) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.